RPM Plus Regional Training Course on Pharmaceutical Management for Malaria, West Africa

Dakar, Senegal, March 27–31, 2006: Workshop Report

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This report was made possible through support provided by the U.S. Agency for International Development, under the terms of Cooperative Agreement Number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

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Strategic Objective 5

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About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen pharmaceutical and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Recommended Citation

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Shretta, R., K. Webb, W. Kabuya-Mutshipayi, T. Ndoye, and M. Diara. 2006. *RPM Plus Regional Training Course on Pharmaceutical Management for Malaria, West Africa, Dakar, Senegal, March 27–31, 2006: Workshop Report*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

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CONTENTS

ACRONYMS

ACT	artemisinin-based combination therapy
AS/AQ	artesunate-amodiaquine
CQ	chloroquine
FDC	fixed-dose combination
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practices
HMM	home-based management of malaria
IMCI	Integrated Management of Childhood Illness
IPT	intermittent preventive treatment
ITN	insecticide-treated net
MMSS	Malaria Medicines and Supply Service
MSH	Management Sciences for Health
NDS	National Drug Store [Liberia]
NMCP	National Malaria Control Programme
PNA	Pharmacie Nationale d'Approvisionnement [central medical stores, Senegal]
PNLP	Programme National de Lutte contre le Paludisme [National Malaria Control Program, Senegal]
RBM	Roll Back Malaria
RDT	rapid diagnostic test
RPM Plus	Rational Pharmaceutical Management Plus (Program)
SP	sulfadoxine-pyrimethamine
STGs	standard treatment guidelines
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
USD	U.S. dollar
WHO	World Health Organization

ACKNOWLEDGMENTS

The authors express their sincere appreciation to the Programme Nationale de Lutte contre le Paludisme [National Malaria Control Program], the Pharmacie Nationale d'Approvisionnement [central medical stores], and the Ministry of Health, Senegal, for their commitment to enabling the Regional Training Course on Pharmaceutical Management for Malaria to be held in Dakar, Senegal, from March 27 to 31, 2006, as well as to the U.S. Agency for International Development (USAID) Mission to Senegal for its support. In particular, the authors wish to acknowledge the enthusiasm of all participants and the valuable contributions made by attending malaria and pharmaceutical management managers and staff members who provided essential, practical on-the-ground perspectives and experiences.

This workshop was conducted by the Rational Pharmaceutical Management Plus Program of Management Sciences for Health and funded by USAID through core Strategic Objective 5 funds.

EXECUTIVE SUMMARY

The Regional Training Course on Pharmaceutical Management for Malaria held in Dakar, Senegal, March 27–31, 2006, provided a forum for major stakeholders from malaria control and essential medicines programs, central medical stores, departments of pharmacy, and national quality control laboratories of 13 countries to develop their capacity in managing medicines and supplies for national malaria control programs. Thirty-eight participants attended the course from Benin, Burkina Faso, Cameroon, Côte d'Ivoire, The Gambia, Ghana, Guinea (Conakry), Liberia, Mali, Niger, Nigeria, Senegal, and Togo. The course provided information and hands-on practice to facilitate national program managers' understanding and implementation of basic pharmaceutical management concepts and methods as well as the monitoring the implementation process in the context of pharmaceutical management.

Workshop materials focused on pharmaceutical management for malaria, particularly the selection and quantification of antimalarials, procurement, distribution, quality assurance, rational use, and monitoring and evaluation. Participants learned practical approaches for applying key concepts in monitoring the pharmaceutical management cycle. Because so many West African countries have recently adopted and are moving toward implementing new malaria treatment policies, the role of monitoring and evaluation to inform implementation processes and the rollout of artemisinin-based combination therapy policy was highlighted throughout the course. By the end of the course, participants were able to understand basic pharmaceutical management theories, apply them, and establish mechanisms for managing antimalarials and related supplies and also identify key performance indicators for monitoring implementation of malaria case management programs.

The workshop consisted of presentations, discussions, and group exercises. The design was highly participatory, and the exchange of skills and experience among participants added valuable depth to the learning process. The workshop was conducted predominantly in French with English interpretation, and course materials were made available in English and French. Course materials were developed by the Rational Pharmaceutical Management (RPM) Plus Program.

In addition, country program managers developed national improvement plans for pharmaceutical management to use as advocacy tools in gaining support of partners for achieving desired ACT implementation goals. These plans will also be used as a basis for follow-up in countries in which RPM Plus has a presence to measure the effect of the course and to monitor progress in achieving the milestones and outcomes set by the participants.

The course provided a rich source of information for building RPM Plus regional technical activities supporting malaria control.

INTRODUCTION

Background

The Regional Training Course on Pharmaceutical Management for Malaria for the West African region took place March 27–31, 2006, at Le Meridien President Hotel in Dakar, Senegal. Thirty-eight participants attended the training course. Attendees came from national malaria control programs, essential medicines programs, pharmacy departments, procurement departments, and central medical stores in 13 malaria-endemic countries in the West African region: Benin, Burkina Faso, Cameroon, Côte d'Ivoire, The Gambia, Ghana, Guinea (Conakry), Liberia, Mali, Niger, Nigeria, Senegal, and Togo. Additional organizations represented included the World Health Organization (WHO) Guinea country office, the United Nations Development Programme (UNDP) Global Fund Project Guinea country office, Malaria Medicines and Supply Service (MMSS) of the Roll Back Malaria (RBM) Partnership, and the U.S. Agency for International Development (USAID) Mission to Senegal.

The workshop was held at the same time as a Regional Malaria Program Implementation Workshop organized by the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria (GFATM). This timing permitted the workshop to benefit from a presentation by two GFATM portfolio managers for the West and Central Africa region, affording participants the opportunity to direct questions related to malaria grant implementation and artemisinin-based combination therapy (ACT) procurement under GFATM grants to the GFATM portfolio managers.

The overall goal of the Pharmaceutical Management for Malaria course was to build regional capacity and increase knowledge and awareness of the elements of pharmaceutical management that affect access to and rational use of antimalarial medicines. These skills are particularly critical because a majority of countries in the region are currently transitioning to new ACTs that require a more systematic approach to pharmaceutical supply management due to the challenges particular to these products (that is, short shelf life, hygroscopic properties, and cost).

The course was organized by the RPM Plus Program of Management Sciences for Health (MSH) in collaboration with the Senegal Programme National de Lutte contre le Paludisme (PNLP, the national malaria control program), the Pharmacie Nationale d'Approvisionnement (PNA, the central medical stores), and the Ministry of Health (MoH) of Senegal; the MSH Senegal country office; and USAID.

Rationale for the Training Course

More than 80 percent of the clinical cases of malaria each year occur in Africa, with much of the burden affecting children under five years of age. The landscape of malaria chemotherapy is further complicated by growing parasite resistance to commonly used first-line therapies. As a result, WHO recommends that countries changing their first-line therapy should opt for the more effective ACTs. Consequently, many countries in the region are at various stages of implementing the policy change. However, there is little experience with ACTs in Africa.

Furthermore, the medicines are expensive—approximately 25–50 times more costly than the older generation of antimalarials. In addition, ACTs differ significantly from chloroquine (CQ) and sulfadoxine-pyrimethamine (SP), requiring a systematic approach to their management. These differences include a short shelf life, bulky packaging necessitating large storage areas, and multiple prepackaging requirements for the various age groups. These properties put more pressure on endemic countries to have in place a systematic approach to antimalarial medicine supply. Moreover, the availability of increased resources from GFATM has led to the procurement of large volumes of commodities, putting pressure on national systems to absorb and effectievely implement the distribution of the products to the points of use.

RPM Plus, in partnership with the PNLP, the MoH of the Republic of Senegal, the Malaria Action Coalition, and the USAID Mission to Senegal, conducted this regional training course on pharmaceutical management for malaria to develop national and regional-level capacity to address pharmaceutical management issues of new antimalarial therapies within the West African region.

Training Course Objectives and Expected Outcomes

The objectives of the training course were to—

- Apply appropriate criteria and select necessary first- and second-line medicines and supplies for national programs, taking into consideration WHO recommendations
- Apply good procurement practices to antimalarial medicines
- Select an appropriate method for quantification, identify appropriate sources for data, and carry out an estimation of antimalarial medicine needs using the method selected
- Establish technical specifications and appropriate mechanisms of supply to assure the quality of medications and commodities procured and used in national programs
- Establish the appropriate mechanisms to guarantee that medicines and supplies are distributed to health services at the right moment and in adequate quantities
- Establish appropriate mechanisms for ensuring rational use of antimalarial medicines
- Establish monitoring mechanisms for availability and use of antimalarials

The expected outcomes of the training course were that participants would be able to—

- Apply appropriate criteria in the selection of first- and second-line medicines and supplies
- Apply good practices for the procurement of antimalarial medicines
- Increase capacity for conducting an estimation of antimalarial medicine needs using appropriate methods and sources of data

- Apply appropriate mechanisms for assuring quality of antimalarial medications
- Establish appropriate mechanisms to ensure the effective distribution and uninterrupted supply of antimalarial medicines to health facilities
- Establish appropriate mechanisms for ensuring rational use of antimalarial medicines
- Establish mechanisms for monitoring the availability, quality, and appropriate use of antimalarials

METHODOLOGY

The Regional Training Course on Pharmaceutical Management for Malaria for the West African region was a five-day course designed to be highly participatory to provide an opportunity for the exchange of skills and experience among participants as an added dimension of the learning process.

The workshop sessions used a combination of the following methods—

- Presentations
- Discussions
- Group exercises
- A field activity

The training course consisted of nine sessions—

Course Overview and Objectives
Session 1: Introduction
Session 2: Selection
Session 3: Procurement
Session 4: Quantification
Session 5: Storage, Distribution, and Inventory Management
Session 6: Quality Assurance
Session 7: Rational Medicine Use
Session 8: Monitoring and Evaluation

RPM Plus staff members facilitated the workshop, using training course materials developed by RPM Plus. The workshop was conducted primarily in French with English interpretation. Materials were available in both languages, and presentations were projected simultaneously in both French and English. Simultaneous interpretation to and from English was provided during presentations, discussions, group exercises, and the field activity.

Participants made presentations to share experiences on particular aspects of implementation within the context of their program. Field visits were organized on the last day of the workshop to the central medical stores (PNA), the Senegal National Quality Control Laboratory, Mbao Health Center, and Mbao Health Post. Participants took the opportunity to apply the knowledge gained during the course to develop and apply indicators for monitoring and evaluation of various aspects of pharmaceutical management for malaria.

A representative from the MMSS of the RBM Partnership in Geneva made a presentation on availability of ACTs and rapid diagnostic tests (RDTs) and how MMSS can assist countries with their procurement processes. During the week, MMSS addressed questions and concerns from participants on procurement and its costs.

Participants worked on national improvement plans throughout the week. The plans will be used as the basis for follow-up to evaluate the course's effectiveness and to determine areas of technical assistance that may be needed to overcome any bottlenecks in the implementation process.

WORKSHOP PROCEEDINGS

Welcome and Introduction

Thidiane Ndoye of RPM Plus welcomed course participants and provided a brief background on the course.

After Mr. Ndoye introduced the guests of honor, participants and partners introduced themselves. Invited guests included—

- Mr. Bradley Barker—Health, Population and Nutrition Team Leader, USAID, Senegal
- Dr. Farba Lamine Sall—Guest of Honor, Chief of Staff, MoH, Senegal

Mr. Barker welcomed participants and visitors to Senegal. He reminded participants of the country's malaria statistics and emphasized the need for a concerted effort to mobilize resources and to work together if any sort or progress is to be achieved. He acknowledged Senegal's revised malaria treatment policy recommending artesunate-amodiaquine (AS/AQ) as a first-line antimalarial treatment. Mr. Barker noted some of the challenges to ensuring access and availability of these new medicines to all, including the cost of the new medicines and their special storage conditions, short shelf life, supply, and effective use. Training was highlighted as an essential component to ensure proper and effective use of the medicines. Mr. Barker encouraged participants to take advantage of the opportunity to be with colleagues from other nations in the region to learn from one another how they can plan and implement an efficient pharmaceutical supply and management system.

Dr. Sall, the Senegal MoH Chief of Staff and guest of honor, acknowledged that Senegal is fortunate to benefit from support programs aimed at ensuring access to the new and more-effective antimalarial medicines. He acknowledged that the country recognized that funding was not the only problem facing malaria control. The rational management of medicines to achieve effective treatment means that health professionals must be trained to handle the new medicines. The initiative of RPM Plus and its collaborators to organize this course was commended because it allowed for and encouraged exchange of information and experiences in pharmaceutical management among the participating countries.

Plenary Presentations

Course Overview and Objectives

Presenter: Thidiane Ndoye

The objectives of this workshop were as follows—

- To apply appropriate criteria and select necessary first- and second- line medicines and supplies for national programs, taking into consideration the WHO recommendations

- To apply good procurement practices to antimalarial medicines
- To select an appropriate method for quantification, identify appropriate sources for data, and carry out an estimation of antimalarial medicine needs using the method selected
- To establish technical specifications and appropriate mechanisms of supply to assure the quality of medications and commodities procured and used in national programs
- To establish the appropriate mechanisms to guarantee that medicines and supplies are distributed to heath services at the right time and in adequate quantities
- To establish appropriate mechanism for ensuring rational use of antimalarial medicines
- To establish monitoring mechanisms for availability and use of antimalarials

The course outline and methodologies to be used in this workshop were described.

Plenary Discussions on Course Objectives and Expectations

Participants were given the opportunity to express their expectations of the training course. The following is a summary of participant expectations and needs—

- Mastery of quantification methods
- Benefit from other country experiences
- Avalability and sustainability of ACTs
- Access to new antimalarial treatments
- Quality assurance
- Private sector experience
- Different approaches to ACT introduction
- Implementation of new treatment protocol

Session 1. Introduction

Presenter: Thidiane Ndoye

This session introduced the general concept of pharmaceutical management and the management of malaria medicines and supplies in particular, with an emphasis on the differences in the management of malarial commodities compared to other pharmaceuticals.

The pharmaceutical management cycle was used to graphically illustrate the interdependent relationships among various activities—selection, procurement, distribution, and use of malaria medicines within the existing policy and legal framework. Careful management and coordination of those activities are necessary for the cycle to function optimally. By understanding the elements of pharmaceutical management and the challenges presented by antimalarial medicines and current approaches to treatment, managers will be able to improve the efficiency of their programs, aim for the most rational use of medicines, and develop beneficial relationships with the private sector, thus ensuring availability of malaria medicines to the public. Although each country present at the course had a unique set of challenges and opportunities, the elements were generically described and could be adapted to specific country contexts.

A framework was presented on how to implement a change in malaria treatment policies to incorporate the use of ACTs.

Upon completion of this session, the participants were able to—

- Define each of the components of the pharmaceutical management cycle and its relationship to the other components
- Discuss the importance of pharmaceutical management for the success of malaria programs
- Discuss the challenges to effective antimalarial commodity management
- Discuss how the management of antimalarials differs from that of other pharmaceuticals
- Identify the effect of pharmaceutical management practices on availability and quality of malaria medicines

Plenary Discussions on Managing Medicines and Supplies

The plenary discussion focused on quantification and the ongoing challenge that this activity poses to many countries. Senegal expressed concern related to donors and the pharmaceutical management cycle and the effect of not respecting each step of the cycle. Participants also stressed the importance of a well-structured procurement system with appropriate coordination and harmonization between partners and donors involved in procurement. Guinea raised the issue of diagnosis as another major challenge because many countries have typically relied upon clinical diagnosis of malaria, resulting in overdiagnosis. However, because of the high cost of

ACTs, a need exists to more accurately diagnose malaria to reduce overdiagnosis and uncessesary treatment with ACTs.

All participants agreed that the recall of expired medicines and old first-line treatments is a challenge and will require a clear policy and system for effective recall. In addition, issues surrounding the black market were discussed.

Group Activity

The session was followed by a group activity where the participants, in country groups (grouped by country), evaluated and identified the main problems and weaknesses their countries have in pharmaceutical management. Participants also identified the areas they would like facilitators to emphasize during the course. Plenary presentations were made by participants from Togo and The Gambia to provide feedback on their discussions.

Session 2. Selection

Presenter: Willy Kabuya

This session focused on the process of evidence-based selection of first-line treatment policies for malaria, taking into consideration factors such as parasitic resistance to the various medicines being considered, efficacy, cost, quality, adverse effects, acceptability, and the system's management and distribution capabilities. Program managers were reminded to carefully balance need against resources and ease of implementation. In addition, recommendations from international experts such as WHO need to play a part in the treatment selected.

Upon completion of this session, participants were able to—

- Discuss the basic principles of selection of appropriate essential antimalarial medicines
- Define the WHO's recommendations for treatment of *Plasmodium falciparum* and *P. vivax* malaria
- Discuss the process of selection of first- and second-line treatments for malaria
- Discuss the challenges for selection of first- and second-line antimalarial treatments
- Define essential medicines lists and standard treatment guidelines (STGs) and their relationship to each other

Plenary Discussions on Selection

The restrictions related to ACT procurement using GFATM grant monies were raised, including WHO prequalification or internationally recognized Good Manufacturing Practices (GMP) certification. The additional 3 percent fee that WHO charges to process Coartem® orders was also mentioned because it adds to the already high cost of the medicines. Remy Prohom of MMSS clarified that pharmaceuticals procured under GFATM grants are not considered

donations and that the 3 percent charge is for handling. The question of manufacturers and suppliers of AS/AQ was raised, because Coartem is the only ACT that has been prequalified by WHO. Workshop facilitators explained that the GFATM procurement policy for prequalified products, particularly with regard to single- or limited-source products, would be reviewed in an upcoming session, which should clarify this topic. Cameroon suggested a need for prequalification of generic manufacturers to lower the cost of ACTs, making them more affordable. Mali added that some procurement problems arise because of lack of involvement of the central medical stores in each stage of the procurement cycle.

Experiences with Antimalarial Medicine Policy Change and Selection of First- and Second-Line Treatments

Mali

Dr. Barasson Diarra presented Mali's experience with the antimalarial policy change process and the first- and second-line antimalarial selection process. In 2000, Mali revised its malaria treatment policy and developed a new malaria strategy for 2001–2005. In 2004, discussions began on changing the malaria treatment policy to adopt ACTs, and the new policy was adopted in 2005. Mali has selected both AS/AQ and artemether/lumefantrine as the new first-line antimalarial treatment. The new policy also includes use of RDTs for diagnosis confirmation, and case management for children under five will be done using the Integrated Management of Childhood Illness (IMCI) approach. Mali's second-line treatment is quinine or artemether monotherapy where quinine is contraindicated. Mali has adopted intermittent preventive treatment (IPT) for pregnant women using SP. Other prevention and vector-reduction strategies include distribution of insecticide-treated nets (ITNs), indoor residual spraying, use of larvacides, and environmental cleanup. The National Malaria Control Program (NMCP) conducts operational research to inform policy revisions and changes as well as monitoring and evaluation to understand the effect of interventions on morbidity and mortality caused by malaria.

Benin

Dr. Marie-Agnès Agboton shared Benin's experience in changing its malaria treatment policy and first- and second-line treatment selection process. Increasing resistance to chloroquine and SP has necessitated a change in Benin's malarial treatment policy. During a consensus-building workshop, Benin adopted SP for IPT and use of ITNs for prevention of malaria in pregnancy. Benin has adopted artemether/lumefantrine for simple malaria and AS/AQ in cases of unavailability or intolerance of artemether/lumefantrine. The case management policy for simple malaria is to prescribe ACT with or without biological confirmation. For serious malaria, health staff members are trained to diagnose; pregnant women with malaria are always considered as serious malaria cases. Benin has a plan to progressively recall the stock of chloroquine in country as ACTs are rolled out. WHO and the United Nations Children's Fund (UNICEF) are procuring the ACTs for Benin using GFATM grant money.

Plenary Discussion following Mali and Benin Presentations

Some discussion took place on the use of co-trimoxazole along with SP for HIV-positive pregnant women. The intent of using co-trimoxazole as well as the number and timing of SP doses for HIV-positive pregnant women were clarified. Guinea also raised some issues and challenges it has experienced regarding distribution and use of ITNs. These challenges include a discrepancy between the size of the bednets and the size of the local beds as well as a misunderstanding that bednets are used, and therefore only needed, in urban areas, as well as the problem of periodic nonusage.

Session 3. Procurement

Presenter: Thidiane Ndoye

This session reviewed the standard methods of the procurement process and the resources (organizational components) that a supply system must have to procure medicines and supplies at the lowest possible total cost.

The session outlined some procurement processes and requirements of GFATM, particularly in relation to how they affect national-level procurement of ACTs and other related antimalarials (procured using GFATM resources).

By the end of the session, participants were able to—

- Identify and describe the steps in the procurement cycle
- Compare the advantages and disadvantages of the four alternatives for purchasing medicines
- Recognize the characteristics of a good pharmaceutical procurement system
- Identify potential problems in accepting medicine donations
- Discuss challenges in procuring malaria supplies

Plenary Discussions on Procurement

Because the ACTs currently available are available only as tablets, the question of pediatric presentations was raised. Somewhat related to this question, Guinea asked about the plan for a fixed-dose combination (FDC) of AS/AQ. Facilitators confirmed that AS/AQ is currently available only as a co-blistered formula, but that an FDC is expected by the end of 2006, along with a pediatric presentation. Guinea also asked about the shelf life of ACTs and the effect of the long procurement process on shelf life. Dr. Ndoye explained that according to WHO, ACTs that arrive in countries should have at least 18 months' shelf life remaining before expiry; however, because of this short shelf life, all the elements of the distribution cycle must be well prepared before the ACTs arrive in country. Many participants raised the question of sustainability of ACTs—how will they continue to procure ACTs when GFATM funding ends? Each country will

have to examine the resources available and determine a way to continue to procure and make ACTs available for malaria treatment.

Experience with GFATM Procurement Procedures

Liberia

Ms. Yah Zolia presented Liberia's experience with GFATM procurement procedures and explained that international nongovernmental organizations working in Liberia were responsible for initiating the change in the malaria treatment policy during the complex emergency period in 2003. Liberia recommends AS/AQ as first-line treatment for uncomplicated malaria, quinine as second-line treatment, and artemether for severe malaria. Some of the challenges associated with the new treatment policy include the high cost and availability of the selected antimalarial, as well as a reluctance of both clinicians and patients to accept the new medicine, and a lack of adequate information about the new medicine.

Liberia was awarded a grant for 12 million U.S. dollars (USD) for malaria in 2003 by GFATM. The NMCP was responsible for selection and quantification of need, while the UNDP is responsible for procurement of ACTs under this grant. The National Drug Store (NDS) is responsible for storage and distribution of the ACTs. Challenges to ACT implementation include the limited storage capacity in country, the difficulty of establishing efficient distribution systems rapidly, the lack of a plan for ACT financing after the end of GFATM support for ACT procurement, and the late involvement of the private sector in the policy change process. Delays with the initial procurement resulted in delayed implementation, and an inadequate supply of adult doses and RDTs resulted in stock-outs (one month). The initial quantification was based on assumptions because of a lack of morbidity or consumption data. Currently, quantification is based on consumption data from health facilities, and the quantification is done in collaboration with the NDS. Liberia uses RDTs to confirm diagnonsis, though when RDTs or microscopy are not available, clinical diagnosis is relied on. When a patient with a fever that is not the result of a respiratory infection has a negative result using an RDT, ACTs are prescribed to treat what is presumed to be malaria. Although Liberia's pharmacovigilance system is not functional, health service providers are being trained to report any reactions or anomalies observed during treatment concurrently with implementation of the new policy.

Senegal

Dr. Mamadou Lamine Diouf presented Senegal's experience in changing its malaria treatment policy and in using the GFATM procurement procedure. Following evidence of chloroquine resistance, the malaria treatment policy was changed during a consensus workshop in June 2003. During a two-year transition phase Senegal used amodiaquine/SP as the first-line treatment. Following this transition period, AS/AQ was selected as first-line treatment for uncomplicated malaria, with artemether/lumefantrine as second-line treatment. Senegal received a GFATM Round 4 grant that included funds for ACT procurement and planned ACT introduction for the last quarter of 2005. The ACTs were introduced in the public sector health system through the traditional circuit in early 2006. Under the GFATM grant both ACTs and RDTs were purchased by WHO, while UNICEF manages the procurement of ITNs. ACTs are being distributed through

the public health system and sold to patients at a reasonable price (approximately USD 0.60–1.25 per treatment dose). Old stocks of chloroquine were recalled and destroyed following an official letter from the MoH.

Availability of ACTs and Related Procurement Issues

MMSS/RBM Partnership
Presenter: Rémy Prohom

The clinical needs that should be considered in choosing ACTs as well as the rationale for ACT use were discussed. WHO-recommended combination therapies were presented, and details such as indication for use, manufacturers and cost, buffer stock, and future capacity were provided on artemether/lumefantrine, AS/AQ, artesunate + SP, and artesunate + mefloquine. Participants were informed that although the production of ACTs has been increased to meet growing demand, the importance of taking delivery lead time into consideration when ordering ACTs is paramount. The importance of proper storage of ACTs was also highlighted.

Mr. Prohom also made a brief presentation on the selection of RDTs. He indicated the considerations to account for in ordering RDTs, though the importance of good quality assurance processes after purchase was stressed. This includes quality assurance and monitoring of tests and temperature at each level of the health system and distribution chain.

Group Activity

The session was followed by a country activity during which countries started working on their national improvement plans.

Session 4. Quantification

Presenter: Willy Kabuya

This session outlined the rationale for quantification of antimalarials and identified the methods commonly used for quantification and the data needed. It also looked at the particular issues related to malaria medicine quantification. The four commonly used quantification methods—morbidity, consumption, adjusted consumption, and service-level extrapolation—were described in detail, with discussions on the principles underlying the choice and use of the various methods. When treatment policies are changed, policy makers must take into consideration essential data sources for each quantification method and the weaknesses of the various types of data together with the challenges to the quantification of antimalarials in the context of selecting a new treatment policy, including the assumptions that need to be made in the practical execution of the quantification process.

Participants practiced using examples until they grasped concepts.

By the end of the session, participants were able to—

- Outline the rationale for quantification of antimalarials
- Identify four methods commonly used in the pharmaceutical quantification process and describe their uses, strengths, and limitations
- Recognize data needed to conduct the quantification
- Discuss particular issues related to malaria medicine quantification, including the assumptions that must be made
- Outline the steps for using the consumption and morbidity methods
- Practice the morbidity and consumption-based methods

Plenary Discussions on Quantification

Quantification remains a challenge for countries. Benin noted difficulty related to quantifying the needs for different age and dosage groups. In quantifying needs for artemether/lumefantrine, Benin used morbidity data, although a quantification software package was in the process of being installed. Senegal noted that for children under five and pregnant women, it used morbidity data from available demographic data disaggregated by age. Facilitators noted that where possible quantification of need by region or province is important, because this information will influence the distribution plan. Most countries initially quantified using the morbidity method because of the new treatment and a lack of consumption data, though future quantifications should use the consumption method. Senegal explained that its quantification takes into account both the public and private sectors and that national treatment guidelines are the same for the public and the private sectors. Senegal works with the private sector to assess consumption and estimate the private sector needs. Additional discussions focused on the adjusted monthly consumption formula and how to deal with atypical months that have unusually high consumption. The review period should be long enough to provide an average monthly consumption and should therefore account for any atypical months.

Session 5. Storage, Distribution, and Inventory Management

Presenter: Kathy Webb

This session discussed the elements in a distribution system—including its design (centralized or decentralized), the information system, the storage conditions, the delivery mechanism, and inventory management—and analyzed each of those elements while discussing a variety of options for improving the efficiency of the entire system.

By the end of the session participants were able to—

- Discuss the various components of the distribution cycle

- Discuss the principles of good storage, distribution, and inventory management
- Identify the inefficiencies in participants' distribution, storage, and inventory management systems
- Discuss alternatives for improving the efficiency of storage, distribution, and inventory management systems
- Calculate and discuss inconsistencies between physical inventory and recorded quantities

Plenary Discussions on Storage, Distribution, and Inventory Management

Participants were referred to *Managing Drug Supply*,[1] which was distributed to each country, for a complete list and discussion of Incoterms.[2] When the issue of developing a system to redirect medicines near expiry was raised, Mali explained that although it does not have a formal system, in the past it has redirected medicines from a low use zone to one with greater need and use to avoid expiry of the medicines on the shelf. Nigeria mentioned that in discussing the distribution cycle and in-country transportation, in addition to issues related to overland transportation, issues related to transport by water and air should also be discussed because many countries use a variety of transportation methods to distribute pharmaceuticals, and each presents particular challenges.

The discussion continued on the private sector and how to involve the private sector in the transition to new malaria treatment policies and ACT implementation. Commonly, a significant proportion of populations bypass the public sector health system and go directly to private pharmacies and providers for malaria treatment; thus, it will be critical to engage the private (health) sector in the ACT implementation process to ensure adherence to the new malaria treatment policies and to reduce use of monotherapies. ACTs should be made available in both the public and private sectors at affordable prices for everyone. The private commercial sector might also be engaged in ACT implementation to resolve problems in the storage and distribution of ACTs. For example, in many countries the central medical stores are already near or at capacity and do not have sufficient warehouse space available to store large quantities of ACTs. One option would be to modifiy the traditional central medical stores model to deal with this problem, contracting out storage and inventory control and possibly distribution to a private sector partner.

Presentation by GFATM on the Regional Malaria Meeting and Discussion

Mr. Mark Willis and Mr. Hans-Dieter Zweschper made a brief presentation on the concurrently running GFATM/RBM West and Central Africa Regional Malaria Workshop and responded to a variety of questions posed by the participants. The question about continued financing from

[1] Management Sciences for Health and World Health Organization. 1997. *Managing Drug Supply*. 2nd ed. West Hartford, CT: Kumarian Press.

[2] Incoterms is an abbreviation of International Commercial Terms, which were first published in 1936 by the International Chamber of Commerce. Since that time there have been six different revisions and updates to the Incoterms. The Incoterms provide a common set of rules for the most often used international terms of trade.

international donor agencies and partners was raised, and GFATM responded that countries will need to advocate to donor agencies and partners to continue to provide the necessary financial support to ensure continued availability of ACTs, antiretrovirals, and antituberculosis medicines. Guinea asked about prequalification of additional ACT manufacturers and the availability of generic ACTs in the future. GFATM noted that it has defined two levels of approval with respect to GFATM financing, prequalification and medicines established by governments. Mr. Zweschper added that GFATM tries to increase the number of manufacturers prequalified and that GFATM applies the same policy as the government regarding generic medicines. He also noted that GFATM does not have restrictions related to the procurement and purchase process—country central medical stores and procurement agencies are free to operate as normal. However, he did note that much depends on the situation in country and local procurement capacity. The primary goal is to get ACTs out to the populations.

The discussion continued on GFATM's role in determining partner responsibilities related to the procurement and distribution process and ongoing challenges specific to some of the countries present. GFATM encouraged participants to engage all in-country players and other international donors to determine the best way forward for the fight against malaria and to ensure continued funding. Mr. Willis also noted that GFATM funds both preventive and curative activities, as well as public and private sector–focused programs, so the burden is on the recipient countries to propose the best mix to meet the needs of their population.

Experience with ACT Implementation

Ghana

Sylvester Segbaya presented Ghana's experience with ACT implementation and challenges it has confronted along the way. Ghana selected AS/AQ as first-line treatment for uncomplicated malaria, while retaining quinine as first-line treatment for severe malaria. Ghana began the policy change and implementation process in 2004, though some aspects of the transition took a year to finalize. To improve adherence to treatment regimens, Ghana mandated that the different strengths of each component of the combination would be color coded and that all tablets would be scored. It also decided to have a transition period of one year, during which CQ, SP, and AS/AQ would be available, though use of CQ and SP would be gradually discouraged and reduced. Deregulation of artesunate from prescription-only status was also necessary so that it could be dispensed by nonpharmacists, increasing its widespread availability and making it available for home-based management of malaria (HMM). Although Ghana decided to initially import AS/AQ, its plan was for local pharmaceutical producers to reengineer the manufacturing facilities to produce AS/AQ locally while winding down production of CQ during the transition period. WHO/Ghana is assisting local manufacturers in the prequalification process because GFATM policy restricts purchase of ACTs to prequalified or GMP facilities. In the meantime, training of all health service providers in the public and private sectors on the new malaria treatment policy has been ongoing since September 2005. Implementation of AS/AQ began in October 2005 through procurement of 1.8 million doses and tablet cutters. The NMCP and Health Promotion Unit designed and launched intensive communication campaigns to run concurrently with initial implementation. They also put in place a pharmacovigilance system to monitor adverse drug reactions at all levels of the system.

Some of the challenges encountered along the way include the slow rollout of training and ACTs in some districts and poorly timed introduction of locally produced AS/AQ in the private sector. Subsequent withdrawal of 600 mg amodiaquine and 200 mg artesunate tablets from the private sector market and the consequent negative publicity for the medicine has created additional hurdles to the transition. As a result it has been difficult, and will likely continue to be difficult, to assure quality and restore confidence in locally manufactured AS/AQ. Currently, no clear solutions exist on how to fill the public-private sector price gap for AS/AQ. The absence of appropriate pediatric dosage formulations in public sector facilities continues to pose problems as does the issue of patient compliance with the co-blistered formulation. In addition to ensuring continued funding and consequently sustained availability of the new treatment, some health workers remain skeptical, so they need to be convinced of the efficacy of AS/AQ.

Following the presentation, other workshop participants asked several questions. Liberia asked about HMM using AS/AQ as well as whether research had been conducted on parasite elimination using a split dose (half the treatment dose taken in the morning and evening) compared with a single dose taken once a day. Mr. Segbaya responded that Ghana has not yet started HMM with AS/AQ; they are only training health providers at this point. Regarding splitting the dose, Mr. Segbaya explained that Ghana began with single doses, but that during the training health providers insisted on administering the treatment in two separate doses.

Guinea asked about pharmacovigilance and RDTs being used. Ghana has not introduced RDTs, because it is relying on clinical diagnosis; however, laboratories that can conduct biological diagnosis are available. Ghana is monitoring adverse drug reactions in patients at five different levels, including public health providers and other RBM partners.

Group Activity

This session was followed by a group activity session to monitor inventory management and ascertain stock-outs.

Session 6. Quality Assurance

Presenter: Rima Shretta

In this session, quality assurance and the different approaches to it were clarified. The session expanded the participants' awareness of global concerns regarding the use of substandard pharmaceuticals and the cause of their proliferation as well as the determinants of pharmaceutical quality. It emphasized both the technical and managerial actions that can be used to ensure pharmaceutical quality.

After completing this session, participants are able to—

- Specify what is meant by quality assurance and quality control in managing the supply of antimalarials and identify the factors that affect their quality
- Describe the components of a comprehensive quality assurance program and practical framework at different levels of responsibility

- Identify practical technical and managerial approaches and procedures to ensure pharmaceutical quality in daily activities

Plenary Discussions on Quality Assurance

Each country has quality assurance concerns, particularly with the transition to ACTs, considering the high cost of the new therapies and the potential for substandard or fake products to enter the market, as has been seen in Asia.

Nigeria raised the issue of testing to ensure the proper dosages of tablets at the peripheral levels. Facilitators responded that most countries are procuring ACTs using GFATM funds and GFATM has a formal policy for procurement of limited or single-source pharmaceuticals, requiring that manufacturers must be WHO prequalified or internationally recognized as adhering to GMP.

Senegal noted that since 2002 it has had an antimalarial quality control program in place at the central and regional levels for both public and private sectors. Ten teams rotate around the country performing tests. Samples that are suspected of being substandard are sent to the national quality control lab for confirmation.

Liberia explained that it has legislation that governs medicine importation and samples are sent to the quality control laboratory. In 2003, Liberia encountered some problems when the national quality control lab was destroyed in the war. However, it is continuing with quality control testing, though it is not easy. Liberia conducts periodic inventory inspections, and substandard medicines are rejected according to WHO guidelines. One challenge, however, is the lack of adequate storage space, which means that some pharmaceuticals are sold even before the inspection takes place.

At the lowest level, what kind of quality control measures can be taken and how can test kits be made available at this level? Putting in place a central mechanism to send samples for rapid testing can reduce the quality control testing costs.

Group Activity

During this group activity participants described the current systems of quality assurance/quality control for antimalarials implemented under their current malaria program.

Session 7. Rational Medicine Use

Presenter: Kathy Webb

This session covered how appropriate mechanisms for ensuring rational antimalarial medicine use can be established. It described the medicine use processes from diagnosis to prescribing, dispensing, and patient use and the problems experienced with antimalarials at each level. It also described the factors influencing antimalarial use and discussed appropriate interventions to improve antimalarial medicine use.

After completing this session, participants were able to—

- Define rational use
- Discuss the factors affecting use of antimalarials
- Discuss and apply methods to identify these problems
- Identify effective strategies to promote rational use of antimalarials

Plenary Discussions on Rational Medicine Use

Initial discussions focused on the relationship between the health system and treatment adherence and the effect of different variables within the health system on adherence. For example, if untrained staff members are dispensing medicines, this practice can lead to poor case management and nonadherence to the treatment.

Guinea noted that traditional medicine and herbal remedies should be considered when discussing rational medicine use. RPM Plus responded that although we all know the value of traditional medicine and herbal remedies, problems often exist related to dosages and interaction with modern medicines that can lead to serious secondary effects.

Nigeria mentioned the reservations voiced regarding making ACTs available for home-based management of malaria, particularly because little experience exists of HMM with ACTs. Because of its experience with adverse drug reactions and side effects experienced using HMM with amodiaquine monotherapy, Nigeria decided to wait and observe the quality of ACTs before making them available for HMM.

Liberia shared its experience with adverse drug reactions using a single dose of AS/AQ. A study showed that dosages were being given according to age rather than weight, and with a single dose patients were complaining of severe side effects. Accordingly, Liberia decided to split the treatment into two doses daily with monitoring to make sure the split treatment doe not fail to clear parasitemia.

Group Activity

A case study that provided a scenario on rational medicine use for malaria was given to participants. The participants worked together to respond to various questions posed at the end of the scenario. Some examples of responses were provided to participants at the end of the session and time was given for group discussion of the issues raised in the case study.

Experience with Home-Based Management of Malaria

Nigeria

Dr. Olusola Oresanya presented Nigeria's experience with HMM. Nigeria studied treatment-seeking behaviors and found that nearly 40 percent of sick children under five receive treatment for fever at home, while 35 percent go to a health center for treatment. The remaining 25 percent seek treatment from some other outlet, including private health clinics, traditional healers, or

some other alternate service provider. Nigeria also found that only 6 percent of medicines prescribed or taken were deemed appropriate and that advice from the public health sector is sought only if the treatment given at home is ineffective. The rationale for HMM includes early diagnosis as well as early and appropriate treatment. Nigeria's HMM program is still in nascent stages; training of role-model mothers began in January 2006. Because women are the primary caretakers within the household, women are trained to recognize the signs and symptoms of malaria and dispense appropriate treatment or make referrals to a health facility, if needed. Men are also trained because they provide the finanacial means of seeking treatment.

Some of the challenges identified in designing the HMM strategy include the size of Nigeria, the malaria burden, and the amount of resources needed; current classification of ACTs as prescription-only medicine; access of caregivers to ACTs and the supply chain of ACTs, as well as the challenge posed by managing the phasing out of the old medicines and introduction of ACTs at the household level; understanding by partners and stakeholders of the concept of HMM using ACTs; quality assurance and control issues; and supervision, and monitoring and evaluation. Many actions are being taken to facilitate the ACT implementation process, including HMM using ACTs. Although implementation of HMM in Nigeria is fraught with many challenges, serious efforts are being made to mitigate them to achieve the desired success

Session 8. Monitoring and Evaluation

Presenter: Malick Diara

This session described how, when, and why to monitor the performance of the pharmaceutical management system for malaria. The session briefly covered assessment or diagnosis of pharmaceutical management systems and also provided an overview of methodologies used to evaluate the effect of interventions and the effectiveness of their implementation. The main focus was on monitoring and improving performance through indicator-based methods, supportive supervision, on-the-job training, and capacity building.

After completing this session, participants were able to—

- Differentiate between monitoring and evaluation
- Describe performance monitoring
- Describe the performance improvement process
- Provide information on methods to monitor performance and evaluate the effect of pharmaceutical management interventions
- Identify key performance indicators for monitoring management of malaria medicines and pharmaceutical supplies
- Elaborate on the use of monitoring systems in improving performance of the malaria pharmaceutical management system and evaluate the effect of pharmaceutical management interventions

- Evaluate the quality of the data

- Have an opportunity to become familiar with the concepts of performance monitoring and evaluation through group exercises and fieldwork

Plenary Discussions on Monitoring and Evaluation

During plenary discussions participants shared their country's existing monitoring methods. For example, Liberia develops a verification list for ACTs distributed free of charge that is given to a health center. In Mali, ACTs are distributed to pharmaceutical depots with supervision tools that manage receipts and sales using stock cards. Senegal noted that the division of tasks by level of responsibility is very important as well as the need to decentralize procurement tasks. Senegal also expressed a concern regarding some standard pharmaceutical management indicators, particularly related to interpretation of the indicator and the potential for error in measuring those indicators. Senegal's main concern is with the price indicator as well as the indicator on tender performance. Guinea suggested that a great need exists for evaluation of antimalarial use by patients because a majority of patients cannot explain the treatment dosages. Ghana evaluates medicine dispensing in all districts, and it has found that some patients do not understand how to correctly use the medicine. Ghana also noted that illiteracy is a fundamental factor that influences our work. Ghana found that in hospital pharmacies, treatment and dosage information is not correctly communicated from the dispenser to the patient, thus the dispensing method needs to be considered. Mali agreed that we must ensure that patients understand fully the treatment dosage before leaving the health facility.

Field Exercise

Participants conducted a field exercise during which they selected indicators, prepared instruments, and collected data. This exercise was to challenge participants to think critically about the performance of pharmaceutical management systems and the data that can be collected to make decisions regarding selection, procurement, distribution, availability, and use of antimalarial medicines.

Interpreters were available to assist the English-speaking participants.

Procurement at Central Medical Stores

The focus of the indicators and visit to the PNA was procurement, distribution, and inventory control. The visit was interesting in terms of exchange of experiences, though the countries noted some large differences in practices. Senegal follows four steps to select a manufacturer, and to accelerate the process it puts in place a letter of intention. The PNA sets delivery deadlines that are not consistent with reality—the average delivery delay was four months, which can result in stock-outs. Each medicine presentation has its own stock card. The team compared the physical count to the theoretical inventory from the stock card and found a difference for quinine 200 mg and 400 mg. The explanation for the difference was that sometimes 200 mg quinine is given in place of 400 mg quinine purely by accident or lack of attention to detail. The PNA invoices after the products have already been distributed. Also, the long distribution chain poses problems and

can result in delays. For example, in come countries many letters require many administrative approvals and signatures.

Quality Assurance at the National Quality Control Laboratory

The group to visit the National Quality Control Laboratory identified a number of indicators to evaluate the quality assurance practices in place. They found that lab capacity to test medicines was 95 percent with good reliability of test results. This laboratory conforms to international norms and the staff members are qualified. However, the list of reference manuals used does not follow international standards. The laboratory is responsible for testing of samples, and the lab director signs off on results. A variety of testing methods are possible and the necessary reagents are also available. Nearly all types of tests can be conducted in this laboratory; it is among the most reliable labs in the region. To test a tablet, the lab would need at least seven days, though this length of time depends on the type of test required. The quality control lab has a good relationship with the NMCP, which provides a financial contribution.

Regarding the parallel market, everything that enters and comes from this market is illegal and the origin of medicines is not considered and should therefore not be used. As such, these products are not currently tested by the National Quality Control Lab.

Although the lab is sufficiently equipped to perform a variety of tests and to handle a good numer of analyses, it does not have a costing structure and it receives samples only from within the Senegalese health system. Guinea asked if the lab had ever had nonconformities on the medicine dosages or other specifications. The team responded that the only negative test results were on samples from the informal system. Although the laboratory has the capacity to test and analyze medicines, it does not have a mandate to do so. It is a laboratory that depends on the ministry of health, though it has tried to develop a network with labs in other countries to have an idea of what is going on in the region. The National Quality Control Laboratory also works in collaboration with the Institute Pasteur on research projects.

Field Visit to Mbao Health Center

The team to visit the Mbao Health Center focused on quantification, the ordering system, and the information management system. Among the tools found to be used at the health center was a daily treatment register, but because of a serious lack of time the team found that the health center staff was working on updating the current quarter (Jan. 1–Mar. 31). For all of the products found to have a difference between the theoretical stock and the actual stock (physical count), the explanation could be poorly or insufficiently trained staff. The team noted that sales from the previous day and earlier in the morning had not yet been recorded on the stock card, which can also explain the differences found between the theoretical and actual stock. At the consultation and treatment level, the team noted how the health center quantifies its need for antimalarials. The team found that the quantification is based on the morbidity method, using the number of malaria cases over the total number of consultations to get the percentage of malaria cases for the previous six months. The team found that neither chloroquine nor AS/AQ was available at this health center.

Assessment of Pharmaceutical Management for Malaria in Mbao Health Post

The team that visited the Mbao Health Post found that two of eight health workers at the health post were trained to perform consultations and diagnose malaria. The other health workers have other responsibilities at the health post, including managing the pharmacy, bandaging, and giving shots among other tasks. The team did not find malaria treatment guidelines available, nor was laboratory equipment available for biological diagnosis of malaria. Ten cases of malaria were diagnosed in a week; no percentage of diagnosis was confirmed. The combination of SP/AQ was being used as the first-line treatment, though some use of SP monotherapy occurred.

ANNEX 1. LIST OF PARTICIPANTS

FORMATION REGIONALE SUR LA GESTION DES ANTIPALUDIQUES
27-31 MARS 2006, MERIDIEN PRESIDENT, DAKAR, SENEGAL
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FORMATION REGIONALE SUR LA GESTION DES ANTIPALUDIQUES
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FORMATION REGIONALE SUR LA GESTION DES ANTIPALUDIQUES
27-31 MARS 2006, MERIDIEN PRESIDENT, DAKAR, SENEGAL
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FORMATION REGIONALE SUR LA GESTION DES ANTIPALUDIQUES
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ANNEX 2. COURSE AGENDA

Day	Time	Activity	Presenter/Facilitator
Day 1	8:30–9:00	Registration	
	9:00–9:15	Welcome	MSH/RPM Plus
	9:15–9:45	Opening Ceremony	Senegal Ministry of Health representative; USAID Senegal Mission representative
	9:45–10:15	Introduction of presenters and participants	
	10:15–10:30	**Break**	
	10:30–11:00	Course overview	MSH/RPM Plus
	11:00–12:15	**Session 1:** Introduction to Management of Malaria Medicines and Supplies	MSH/RPM Plus
	12:15–13:00	Group Activity (Worksheet 1.1)	
	13:00–14:00	**Lunch**	
	14:00–14:30	Presentation of Group Activity (2 groups)	Group presentations
	14:30–15:45	**Session 2:** Selection	MSH/RPM Plus
	15:45–16:00	**Break**	
	16:00–17:00	Experiences with antimalarial medicine policy change and selection of first- and second-line treatment	Benin and Mali
Day 2	8:30–8:45	Plenary (questions and clarifications)	
	8:45–10:30	**Session 3:** Procurement	MSH/RPM Plus
	10:30–10:45	**Break**	
	10:45–11:00	Experience with GFATM procurement procedures	Senegal and Liberia
	11:00–13:00	Group Activity (Worksheet 3.1 Begin National Improvement Plan, country groupings)	
	13:00–14:00	**Lunch**	
	14:00–14:45	Procurement and availability of artemisinin-based combination therapies (ACTs)	Malaria Medicines and Supplies Service/Roll Back Malaria (RBM) Partnership
	14:45–16:15	**Session 4:** Quantification	MSH/RPM Plus
	16:15–16:30	**Break**	
	16:30–18:00	Group Activity (Worksheets 4.1 and 4.2)	

Day	Time	Activity	Presenter/Facilitator
Day 3	8:30–9:00	Plenary (questions and clarifications)	
	9:00–10:30	**Session 5:** Storage, Distribution, and Inventory Management	MSH/RPM Plus
	10:30–10:45	**Break**	
	10:45–11:00	Presentation by GFATM	GFATM representative
	11:00–11:15	Experience with implementation plan for ACTs	Ghana
	11:15–13:00	Group Activity (Worksheet 5.1)	
	13:00–14:00	**Lunch**	
	14:00–16:00	**Session 6:** Quality Assurance	MSH/RPM Plus
	16:00–16:15	**Break**	
	16:15–17:30	Group Activity (Worksheet 6.1)	
Day 4	8:30–8:45	Plenary (questions and clarifications)	
	8:45–10:00	**Session 7:** Rational Medicine Use	MSH/RPM Plus
	10:00–10:15	**Break**	
	10:15–11:15	Group Activity (Worksheet 7.1)	
	11:15–11:30	Experience with home-based management	Nigeria
	11:30–13:00	Continue to work on National Improvement Plan (country groupings)	
	13:00–14:00	**Lunch**	
	14:00–15:30	**Session 8:** Monitoring and Evaluation	MSH/RPM Plus
	15:30–16:00	Instructions for the monitoring and evaluation exercise (Worksheet 8.1)	
	16:00–16:15	**Break**	
	16:15–17:30	Group Activity (Worksheet 8.1, preparation for fieldwork)	

Day	Time	Activity	Presenter/Facilitator
Day 5	8:30	Depart hotel for field visits (participants must be ready at 8:15 for a prompt 8:30 departure)	
	9:00–12:00	Fieldwork	
	12:30–13:30	Group Activity (Worksheet 8.1, preparation for presentation)	
	13:30–14:00	**Lunch**	
	14:00–15:00	Presentation of group activity	Group presentations
	15:00–15:15	**Break**	
	15:15–16:45	Continue to work on National Improvement Plan (country groupings-to be submitted to facilitators at the end of the day)	
	16:45–17:00	Closing Remarks and presentation of participant certificates	